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10/643,649	08/18/2003	Jack Chu	PA1515 (MEDT/0018)	5247

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EXAMINER
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NEAL, TIMOTHY J

ART UNIT	PAPER NUMBER
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3731

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06/15/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

**Application No.**

10/643,649

**Applicant(s)**

CHU ET AL.

**Examiner**

Timothy J. Neal

**Art Unit**

3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 05 April 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-29 and 31-48 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-29 and 31-48 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 April 2007 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

This action is in response to the amendments received on 4/05/2007. The affidavit received on 4/05/2007 has been accepted and entered into the record. The amendments to the Specification are deemed proper.

### ***Drawings***

The drawings were received on 10/31/2006. These drawings are accepted because the Examiner considers the drawings to show, according to the Applicant, a double and triple helix. The objection to the drawings has been removed now that all features of the claims are shown.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

**Claims 1-3, 6, 7, 17-19, 40-42** are rejected under 35 U.S.C. 102(e) as being anticipated by Jansen et al. (US 6,579,308).

Jansen discloses an intravascular treatment device, comprising: a stent (2) locatable interior of an aneurysmal site in a blood vessel; wherein the stent supports the aneurysmal site upon deployment by engaging the inwardly-facing surface of the vessel wall, contracts when the aneurysmal site contracts due to healing, and comprises at least one therapeutic agent (Column 2 Lines 49-50). The stent is helical, self-expanding, comprises nitinol, and the stent is deployed by catheter to an aneurysm site (see figures 1-4 and disclosure). Claim 40 is a product-by-process claim and is given no patentable weight.

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**Claims 43-45** are rejected under 35 U.S.C. 102(b) as being anticipated by Ragheb et al. (U.S. 6,096,070).

Regarding **claim 43**, Ragheb et al. discloses a helical stent locatable interior of an aneurysmal site in a blood vessel; wherein the stent supports the aneurysmal site upon deployment, contracts when the aneurysmal site contracts, and comprises at least one therapeutic agent (Col 19 Lines 22-27, Col 6 Lines 39-42 and Col 15 Line 56).

Regarding **claim 44**, Ragheb et al. discloses the stent being biodegradable (Col 7 Lines 29-47).

Regarding **claim 45**, Ragheb et al. discloses the stent comprises poly(orthoester) (Col 7 Lines 29-47).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**Claims 4, 5, 8-16, 20-29, 31-39, and 46-48** are rejected under 35 U.S.C. 103(a) as being unpatentable over Jansen '308 in view of Maass (US 4,553,545), Segal (US 5,755,708), Summers et al. (US 5,772,668), Melzer et al. (US 6,280,385), Ragheb '070, Eisert (US 2005/0192664), Hunter et al. (US 6,333,347), Hunter et al. (US 5,716,981), Narciso, Jr. (US 5,419,760), Vallana et al. (US 2003/0028242), Clouse (US 5,211,658), and Falotico et al. (US 2003/0060877).

Jansen discloses the invention substantially as claimed as stated above. Jansen further discloses the stent comprises a polymer (polyesters and polyurethane) as recited in claims 9 and 12. Jansen is silent on whether these polymers are biodegradable or not. Jansen does not explicitly disclose double or triple helices, the therapeutic agent being covalently linked to the polymer, the polymer being pH-sensitive, the polymer being temperature sensitive, the specific type of therapeutic agent used, wherein the therapeutic agent is contained in microspheres, wherein the therapeutic is applied as a coating the coating further comprising a polymer, the nature of the application of the coating, a second coating, two therapeutic coatings, the

polymer coating being biodegradable, wherein the coating is time-released, the method including a stent graft, and wherein the therapeutic agent is inactive until activated.

**Claims 4 and 5:** Maass, Segal, Summers, and Melzer disclose stents with double helix configurations (see figures of references). Melzer in particular discloses multiple helix configurations. Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Jansen's single helix to include double or triple helices. Such a modification would provide more coverage of the target site, increased surface area for the deliver of drugs, and other advantages as known in the art.

**Claims 8, 9, 11, 12:** Ragheb teaches that a variety of conventional materials can be employed as a base material for a stent, including biodegradable and non-biodegradable materials (Col 7 Lines 18-27). Jansen discloses the polymers for the stent as stated above. Jansen does not disclose the nature of the materials. However, because Ragheb teaches that conventional polymers are known to be either biodegradable or non-biodegradable, the Examiner considers it obvious to modify Jansen's polymers to be either biodegradable or non-biodegradable. Such a modification would in the biodegradable case allow the stent to degrade and thus not need to be removed. If the stent is required to remain within the body indefinitely, a non-biodegradable polymer should be used.

**Claim 10:** Ragheb teaches covalently bonding heparin to the outermost surface of the stent (Col 8 Line 25). When this teaching is applied to Jansen, this heparin would be the therapeutic coating on the outside of the stent. The heparin then helps prevent

clot formation. Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Jansen's stent to include Ragheb's covalent heparin. Such a modification would prevent clot formation. The Examiner also notes that Ragheb teaches the more general principle of using covalent bonds to link drugs to polymers. This teaching can be applied to Jansen when other drugs are to be administered. Basically, the concept is not limited to heparin. Wright teaches that drugs (specifically rapamycin) may be bound to a stent covalently via the Carmeda process (Col 5 Line 65 through Col 6 Line 10). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to use covalent linking to bind the therapeutic agent to the polymer stent. Such a modification provides a strong link to the polymer to allow for the release of the drug as desired based on the application.

**Claims 13 and 14:** Eisert teaches a pH sensitive polymer (Paragraph 64) that expands when contacted with a certain pH. Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Ragheb et al.'s polymer stent to include Eisert's pH-sensitive polymer. Such a modification would allow the stent to expand. Hunter '347 teaches that cellulose acetate phthalate is a pH sensitive polymer (Col 7 Lines 27-58). Therefore, it would have been obvious to use cellulose acetate phthalate as Eisert's pH-sensitive polymer.

**Claims 15 and 16:** Eisert teaches a temperature sensitive polymer (Paragraph 65) that takes on a new shape when heat is applied. Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to

modify Ragheb et al.'s polymer stent to include Eisert's temperature sensitive polymer. Such a modification would allow the stent to change shape upon application of heat. Hunter '347 teaches that pluronics F-127 is a temperature sensitive polymer (Col 8 Lines 41-65). Therefore, it would have been obvious to use pluronics F-127 as Eisert's temperature-sensitive polymer.

**Claims 20-27:** Narciso, Jr. teaches the application of aspirin to a stent to act as an anti-platelet/anti-thrombus drug (Col 5 Lines 55-68). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Jansen's stent to include Narciso's aspirin. Such a modification would reduce clot formation.

**Claims 28, 29, 31, 32, 33, 36, 37, 38, 39, 48:** Hunter '981 teaches polymer microspheres made of polyvinyl alcohol (PVA) and size ranges of up to approximately 120 microns (figures 5-6, 9-10), release profiles of the therapeutic agent including about 1% to about 25% of the therapeutic agent released in the first 10 days (figure 15D), and the coating being a spray from microspheres (17 Lines 7-67 through Col 18 Lines 1-7). Therefore, it would have been obvious to a person having ordinary skill in the art to modify Jansen's stent to include Hunter's microspheres and release profile. Such a modification would allow for a controlled release of a desired amount to the target site.

**Claims 31-36:** Ragheb teaches the therapeutic agent being applied as a coating to the stent (Abstract and Column 7 Lines 55-62); the coating being applied as a film (Col 18 Line 2); a second coating deposited over the therapeutic coating (Fig. 2 Item 20); at least two therapeutic coatings, wherein each therapeutic coating is separated by a

second coating (Fig. 2 Items 18, 22, and 24); the coating being a biodegradable coating (Col 9 Lines 20-67); the polymer being heparin (Col 9 Line 23); the coating being a time release coating (Col 10 Lines 30-35). Multiple coating allow for multiple drugs to be released or the same drug to be released with different time-release characteristics.

Ragheb does not disclose the therapeutic coating further comprising a polymer.

Vallana teaches that polymers are used as carriers for therapeutic coatings (Paragraph 65). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Jansen's stent to include Ragheb's coating including Vallana's polymer. Such a modification provides the advantage of additional control over the release characteristics of the drug. Furthermore, the polymer carrier coating of Vallana is considered a time-release coating being that the therapeutic agent is released over time. It is also noted that Hunter '981 discloses a polymer carrier as stated above. The combination of Hunter '981, Ragheb, and Jansen would apply in the same manner as the combination of Ragheb, Vallana, and Jansen.

**Claims 46 and 47:** Clouse teaches first inserting a stent to an aneurysm site and then inserting a graft (Col 3 Line 46 through Col 4 Line 13). This shows that it is known to deliver a stent before delivering the graft with the stent between the graft and the aneurysm. The Clouse reference discloses the graft traversing the aneurysm in order to prevent pressure on the aneurysm. Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Jansen's method to include Clouse's stent graft. Such a modification would prevent pressure on the aneurysm from blood flow. Obviously, Jansen's stent would need to be inserted

before Clouse's. If not, Jansen's stent would not be able to be located so that it engages the aneurysm. Jansen's stent would act in a similar manner to vaso-occlusive coils and provide drug treatment and other advantages to the aneurysm site. Falotico teaches a therapeutic agent being inactive until it comes in contact with an activating agent (Paragraph 142). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Jansen's agent to include the therapeutic agent and the activation characteristic of Falotico. Such a modification would allow for additional measure of time release.

### ***Response to Arguments***

Applicant's arguments with respect to claims 1-48 have been considered but are moot in view of the new ground(s) of rejection.

The Applicant has argued that the prior rejections did not address a stent that contracts when the aneurysm contracts due to healing. The Jansen reference was designed to be able to do such a thing. The Applicant has also argued that Ragheb does not disclose a helix. The Examiner disagrees. Also, claim 43 does not require a helix. The claim only requires that the stent be helical. The Examiner has pointed to the specific portions of the reference that describe the helical nature of the prior art. The longitudinal member does not preclude the device from being considered helical. The Examiner has addressed the Applicant's arguments concerning self-expanding stents, drugs such as aspirin, and the particular polymers used so that there should no longer be any question of the validity of the obviousness rejections. Also, the Jansen

reference clearly indicates the stent is self-expanding. With most of the arguments being directed to art that is no longer being applied, the Examiner considers the rejections above to sufficiently address the issues of the prior action.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Timothy J. Neal whose telephone number is (571) 272-0625. The examiner can normally be reached on M-F 9:00-5:30.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TJN

  
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PRIMARY EXAMINER  
6/11/07